Subject perceptions of computer-based informed consent for a large, population-based genomics study: The Marshfield Clinic Personalized Medicine Research Project (PMRP)

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Background

Insuring that the consent process is uniform and that all subjects are adequately informed remains a challenge in many research projects. Previous studies of the PMRP subjects showed that although almost all study participants understood the overall goals of the project, they were unsure or incorrect about several key study issues. These issues included: duration of their participation in the study, the fact that their DNA would be stored and the non-disclosure of personal study details. One potential approach is to use computerized consent that implements a Computer Based Training (CBT) paradigm. Relatively little is known about how potential subjects would respond to a CBT consent process. The goal of this study is two-fold:

1) to understand how verbally delivered consents vary from the written consent form
2) to understand subject perceptions regarding CBT consenting.

Methods

A trained research coordinator conducted mock informed consents which were video and audio taped and transcribed. We conducted focus groups with PMRP Community Advisory Group (CAG) members and representative study participants from the public. Focus groups were video and audio taped and transcribed. Mock consents were conducted to document explicitly what the research coordinator would say to deliver a verbal consent. This is important since the CBT will in part replace what the research coordinator says during the verbal consent conversation. The focus groups discussed perceptions about using the CBT instead of a research coordinator for the consent. They also gauged preferences for the type of hardware that participants would best like to complete the CBT on. Types of hardware reviewed included: tablet computers, rugged mini-tablet computers (Touchbooks) and kiosks.

Results

The results from the mock consents documented areas of the consent where subjects had questions for the research coordinator. The research coordinator varied how she conducted the consent from subject to subject, paraphrasing from the text based consent. Researcher observations of the studies showed the overall reading level of consent conducted by the research coordinator to be lower than the text based consent. Feedback from the focus groups showed an indication of resistance to being consented by completing a CBT instead of a research coordinator. They also provided feedback about how they broadly envisioned the CBT interface to look and function. The focus groups preferred the Touchbook type hardware, but indicated that they would not like to stand at it for an long length of time.

Conclusion

Overall, subjects were receptive to the concept of CBT consenting. Subjects had very specific preferences regarding hardware and software behavior. The CBT consent will need to match or have lower reading levels than the consent by research coordinator. The CBT consent will need to offer supplemental information beyond that available in a normal written consent form.

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Final Readings: Personalized Medicine Research Database. Many studies will use this database. Some studies will try to learn what genes are responsible for common diseases and to find which genes predict medication to drugs. Other studies could explore how the environment in which we live and genetic factors work together to cause disease. It is hoped that all of this information will help us learn more about the causes of disease. If we are able to predict disease, we may be better able to prevent or treat disease.

The goal is to have at least 40,000 people enroll in this project. We plan to follow the health of people included in the project. This will allow the people doing the study to follow the health of a large group of people in a relatively geographic area over time.

We are looking at enrolling 40,000 people in the study. We have almost 25,000 now. Notch across a level. This has been going on since 2002, so we have been doing this for quite a while. We are planning on doing reasonably because we have found diseases can change and what we have learned in the last 5 years, we can learn even more in the next 5 years. We want to see diseases as they progress through populations of people.

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A prototype of the CBT consent will be developed. Iterative testing will be conducted on the prototypes. Once the CBT module is ready for production a randomized trial will be conducted to test retention of consent information. Follow up surveys will be given to both participants that were consented by a research coordinator and participants that consented via the CBT module. Differences in retention by age, gender and education level will also be evaluated.

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Many common diseases are influenced by genetics. Even small genetic differences between people may be important in the development of disease and its response to treatment. For example, some people experience bad side effects after taking the same drug while others do not. Disease can also be influenced by the environment in which we live or by our personal behaviors, such as diet.

The main goal of this project is to better understand genetics of human health. The project will try to do this by creating a Personalized Medicine Research Database. Many studies will use this database. Some studies will try to learn what genes are responsible for common diseases and to find which genes predict medication to drugs. Other studies could explore how the environment in which we live and genetic factors work together to cause disease. It is hoped that all of this information will help us learn more about the causes of disease. If we are able to predict disease, we may be better able to prevent or treat disease.

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